Citation:

Aston LM, Stokes CS, Jebb SA. No effect of a diet with a reduced glycaemic index on satiety, energy intake and body weight in overweight and obese women. *Int J Obes* (Lond). 2008 Jan; 32 (1): 160-165.

PubMed ID: 17923862

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate whether a diet with a reduced glycemic index (GI) has effects on appetite, energy intake, body weight and composition in overweight and obese female subjects.

Inclusion Criteria:

Female subjects with a body mass index (BMI) of >25kg/m^2 and fasting plasma insulin concentration >50pmol/L.

Exclusion Criteria:

- Following a weight loss diet or had not been weight stable over the preceding two months (weight change of no more than 2kg)
- Suffered from chronic medical conditions (including diabetes, cardiovascular disease, hypertension (blood pressure >160/100mmHg), malignancy, clotting or bleeding disorders, renal, liver or respiratory disease), anemic, allergic or intolerant to any of the provided intervention foods, pregnant or breastfeeding, taking regular steroids or non-steroidal anti-inflammatory drugs, lipid-lower drugs or anti-coagulants.

Description of Study Protocol:

Recruitment

Recruited from the community.

Design

Randomized cross-over intervention with two consecutive 12-week periods.

Dietary Intake/Dietary Assessment Methodology

- Subjects kept four-day diet diaries at baseline and during the final week of each intervention period and the composition of foods was coded into a database
- For the appetite laboratory investigation, foods eaten were weighed and blood samples were taken.

Blinding Used

Subjects were not informed of the glycemic index differences of the study foods.

Intervention

- Subjects were provided with lower or higher glycemic index (GI) versions of key 'staple' carbohydrate-rich foods, according to intervention period, to incorporate into their habitual diet
- Provided foods included breads, breakfast cereals and rice, plus pasta on the lower GI diet and potatoes during the higher GI period. These 'low' and 'high' GI foods had a mean difference of 28.5 units
- Subjects were instructed to maintain their habitual diets for the duration of the study, but to substitute the supplied foods into their diets on at least three occasions per day in the quantity they would normally consume
- Subjects were given simple advice regarding other foods to chose or avoid, based around the staple carbohydrate choices and excluding reference to pulses, fruits and vegetables to avoid wider dietary change
- Appetite investigation days were performed during the final week of each intervention period (to determine whether high vs. low GI foods at breakfast modulated energy intake two hours and four hours later).

Statistical Analysis

End-point outcome measures were compared within-person using a fixed-effects linear regression model including subjects as variables, into which period was included to check for period effects.

Data Collection Summary:

Timing of Measurements

- Baseline and at the end of each 12-week intervention
- For the laboratory appetite investigation, remaining foods were weighed after consumption of meals or snacks; blood samples were taken prior to breakfast and following breakfast (15, 30, 45, 90 and 120 minutes); hunger and fullness assessed at half-hour intervals and palatability following meals.

Dependent Variables

- Weight
- BMI (kg/m^2)
- Waist circumference
- Body composition [whole body dual energy X-ray absorptiometry (DEXA) scan]
- Plasma glucose, insulin, and non-esterified fatty acids
- 10cm visual analog scale scores regarding hunger, fullness and palatability.

Independent Variables

Intervention (high or low GI diet).

Control Variables

Treatment order.

Description of Actual Data Sample:

- *Initial N:* 26
- *Attrition (final N):* 19
- *Age:* Mean of 51.9 years (SD, 7.6; range, 34-65 years)
- *Ethnicity:* Not reported
- *Other relevant demographics:* Not reported
- *Anthropometrics:* Mean BMIof 33.1kg/m^2 (SD, 4.9); mean body fat of 47.8% (SD, 3.5) those who dropped out did not differ from those who completed the study in any baseline measurements
- *Location:* Cambridge, UK.

Summary of Results:

Effect of Dietary Intervention (Low or High Glycemic Index) on Body Weight and Composition (N=19)

Variables	High GI Diet Mean (SD)	Low GI Diet Mean (SD)	P-value of Mean Difference Between Groups
Weight (kg)	89.2 (16.1)	89.1 (15.6)	0.8
Waist* (cm)	106 (0.13)	105 (0.12)	0.4
Fat mass (kg)	42.9 (8.9)	44.54 (9.2)	0.9
Lean mass (kg)	44.6 (5.7)	43.13 (5.6)	0.5
Body fat (%)	47.6 (3.6)	47.72 (3.8)	0.8

* log transformed for statistical analyses.

Key Findings

- There were no differences in energy intake, body weight or body composition between treatments
- All subjects reduced dietary GI on the lower GI diet compared with the higher GI diet, with a mean difference of 8.4 units (P<0.001). Glycemic load was not significantly reduced on the low GI diet due to a small increase in carbohydrate intake
- Short-term appetite investigation:
  - There were no differences at either meal, or in the total energy intake over the day
  - There were no difference in subjective ratings of appetite at any time point between

investigation days
- There were no differences in glucose, insulin and non-esterified fatty acids responses to the lower vs. higher GI breakfasts.

Author Conclusion:

This randomized crossover trial found no evidence to support a beneficial effect of a reduction in GI of the diet on satiety, energy intake, body weight or fatness through simple substitution of staple carbohydrate foods.

Reviewer Comments:

The authors note that there was a modest weight gain during both intervention periods, possible as a function of receiving 'free' food.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	???

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes

2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???

5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes

8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	???
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	???
8.6.	Was clinical significance as well as statistical significance reported?	???
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes